

**Notice of Allowability**

Application No.

10/066,293

Examiner

Kandasamy Thangavelu

Applicant(s)

ASCENZI ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 19 August, 2005.
2. ☒ The allowed claim(s) is/are 1-3,5-18 and 20-39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 8/19/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

## **DETAILED ACTION**

### ***Introduction***

1. This communication is in response to the Applicants' communication dated August 19, 2005. Claims 1-3, 5-18 and 20-26 were amended. Claims 4 and 19 were deleted. Claims 27-39 were added. Claims 1-3, 5-18 and 20-39 of the application are pending.

### ***Examiner's Amendment***

2. Authorization for this examiner's amendment was given in a telephone conversation by Ms. Dianna Goldenson on October 25, 2005.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to the applicants, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. In the claims:

In amended Claim 1, Lines 9-12, "wherein the second order components are used to determine properties of the first order region, and

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wherein a property of the first order region is determined based on the viscoelastic property of the second order component”

has been changed to

-- wherein the second order components are used to determine properties of the first hierarchical order region, and

wherein a property of the first hierarchical order region is determined based on the viscoelastic property of the second order component--.

Replace Claim 17 with:

17. A method of producing a model of bone, comprising the steps of:
- a) specifying a first hierarchical order macroscopic region of a selected bone;
  - b) dividing the macroscopic region into a finite number of elements of second hierarchical order, each element representing empirically derived non-homogeneous second order component comprising one or more osteons, trabeculae, or lamellae;
  - c) assigning a viscoelastic property to at least one second order component and
  - d) determining a property of the first hierarchical order macroscopic region of the selected bone based on the viscoelastic property of the second order components.

Replace Claim 33 with:

33. A method of producing a model of a bone comprising the steps of:
- a) specifying a first hierarchical order macroscopic region of a selected bone;

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b) dividing the macroscopic region into a finite number of elements of second hierarchical order, each element representing empirically derived non-homogeneous second order component comprising one or more alternate and extinct osteons;

c) assigning a viscoelastic property to at least one second order component, wherein the viscoelastic property comprises at least one parameter selected from the group consisting of collagen content, mucopolysaccharide content, hydroxyapatite content, osteocyte content, osteoblast content, and content of porosity fluids; and

d) determining a viscoelastic property of the first hierarchical order macroscopic region of the selected bone based on the viscoelastic properties of the second order components.

### ***Reasons for Allowance***

4. Claims 1-3, 5-18 and 20-39 of the application are allowed over prior art of record.

5. The following is an Examiner's statement of reasons for the indication of allowable subject matter:

The closest prior art of record shows:

(1) a method of accounting for the microstructure of the compact bone when determining the overall macroscopic behavior of the bone, using homogenized approximations; compact bone is a heterogeneous medium exhibiting a multiscale composite structure; it is possible to simulate the macroscopic behavior from the microscopic mechanical characteristics using a homogenized approximation; due to the hierarchical structure of the compact bone in three levels, a three level

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homogenization is used; the model follows two main steps: the first step analyzes the physiological structure of the compact bone using a hierarchical organization; the macroscopic structure is analyzed through the substructures which are further decomposed into further substructures; the mechanical characteristics are then calculated by defining an elasticity tensor for each substructure and computing the overall elasticity tensor from those of the substructure; the analysis assumes the collagen fiber and the hydroxyapatite to be homogeneous (**Crolet**, "Compact bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol 26, No. 6, pp. 677-687, 1993);

(2) application of a two level hierarchical analysis model to predict the anisotropic elasticity of the bone; the bone has a hierarchical structure; on the microstructural level are the osteons which are hollow fibers composed of concentric lamellae and pores; at the ultrastructural level, the fibers are a composite of hydroxyapatite and protein collagen; these specific structural features are associated with various physical properties; the model relates the bone stiffness to the orientation of the applied stress with respect to the osteon axis; the hierarchical structure is analyzed using finite element analysis method (**Lakes**, "Materials with Structural hierarchy", Nature 361, pp. 511-515, 1993); and

(3) a method of determining the mechanical properties and composition of the cortical bone; the relationship between stresses and strains at a particular point in the bone are governed by the material properties of the local bone; biological processes produce changes in the microstructural and compositional characteristics that affect the mechanical properties of the bone; the classification of the bone tissue as cortical or cancellous is based on the bone porosity; cortical bone is a viscoelastic material; its elastic properties and strength are dependent upon

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both the rate and duration of the applied loading; the elastic properties and strength are dependent upon the orientation of the bone microstructure with respect to the direction of loading; repeated loading of the cortical bone causes a gradual and progressive loss of bone stiffness (**Carter et al.**, “Clinical orthopedic and Related Research”, Number 135, September 1978).

None of these references taken either alone or in combination with the prior art of record discloses a system for modeling macrostructural characteristics of a bone, specifically including:

“a second hierarchical order comprising at least one empirically-derived non-homogeneous second order component representing one or more osteons, trabeculae, or lamellae within the macroscopic region, and

wherein a property of the first hierarchical order region is determined based on the viscoelastic property of the second order component”.

None of these references taken either alone or in combination with the prior art of record discloses a method of producing a model of bone, specifically including:

“dividing the macroscopic region into a finite number of elements of second hierarchical order, each element representing empirically derived non-homogeneous second order component comprising one or more osteons, trabeculae, or lamellae; and

determining a property of the first hierarchical order macroscopic region of the selected bone based on the viscoelastic property of the second order component”.

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None of these references taken either alone or in combination with the prior art of record discloses a method of producing a model of bone, specifically including:

“dividing the macroscopic region into a finite number of elements of second hierarchical order, each element representing empirically derived non-homogeneous second order component comprising one or more alternate and extinct osteons; and

determining a property of the first hierarchical order macroscopic region of the selected bone based on the viscoelastic property of the second order components”.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance.”

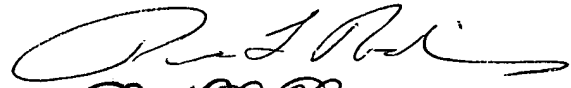
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard, can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to TC 2100 Group receptionist: 571-272-2100.

K. Thangavelu  
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October 25, 2005

  
Paul L. Rodriguez 10/28/05  
Primary Examiner  
Art Unit 2125